case and the subject matter of the Goldberg reference. Applicant represented that an RCE would be filed because Applicant would be remiss not to argue the un-combinability of Goldberg and the instant case from the undersigned skilled artisans knowledge and point of view. This RCE is the result of this decision. The Examiner suggest that Applicant focus on the technical merits of the lack of combination and why the two case are not combinable, what prevents the combination and why Goldberg cannot be successfully substituted to operate in its normal operation in the manner in which the instant case supply chain converts containers.

The Claims 1-30 have been amended to 1) follow the Examiners suggestion (page 6 line 12 of the said office action) to incorporate a "container supply chain conversion" into the "body" claims 5 & 7. The claims have also been amended to recite a vacuum path of the instant case is sealed, but not closed. A distinguishing difference between Goldberg and the instant case. The claims 5 & 7 have been amended to recite the relationship between the vacuum, the path, the force in its relation toward and away from a converted container, and means for allowing air(inlet) into and out of the container neck(air/exchange)material ingress relationships as they so function in the instant case. Applicant believes independent claims 4, 5, & 7 are now in a condition for allowance along with the claims depending therefrom. "To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).* "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)*;. "If an independent claim is non obvious under 35 USC 103, the any claim depending therefrom is nonobvious." *In re Fine 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).*

Applicant maintains its belief that the Examiner was correct in its past allowance of claims that were the subsequently withdrawn from allowance (disallowed) in the last office action. The applicant believes that on the technical and art merits, the Goldberg reference, and the instant case are too remote to be considered combinable. Applicant amends claims 1-30 based on a Festo strategy, of a concern of future litigation, and not for "art of record" subject matter reasons. Applicant knows of no art of record wherein the subject container supply chain conversion, as defined by the manner in which the instant case defines.

This simple novel supply chain container conversion method has escaped the art.

Applicant contends the Examiners remarks, that Goldberg uses the "same container" as a point of 103 rejection, is distilling a jist or thrust of one part of the Goldberg reference in reliance of such a 103 rejection. In this regard the examiner has failed to consider Goldberg "as a whole". In like error, the examiner has failed to consider the instant case "as a whole". Applicant contents, that as a whole, such a broad conclusory statement does not provide the legal basis to ground such a 103 rejection. The heart of Goldberg, and the heart of the instant case are missing from the examiners remarks. Also missing is the comparison of the differences required by the Graham inquiries. The examiner points out similarities, which are founded on hindsight, but fails to point out the requisite differences, which the Applicant point out herein for the record. "Distilling an invention down to a "jist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L.Gore & Associates, inc., v. Garlock Inc., 721 F.2d 1540 220 USPQ 303 (Fed. Cir. 1983).* "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence." *In re Dembiczak, 175 F.3d 994 (1999), In re Rouffet, 149 F.3d 1350, 1357-58 (1998).*

The container supply chain conversion is a simple invention. Just as simple are the reasons why the instant case is not combinable with the Goldberg reference on grounds for a 103 obviousness rejection. Just as simple as a person who takes an automobile into the shop for an oil change, expecting to have the oil changed. The mechanic drains the oil and gives the car back to the customer without oil. No artisan would consider aborting an oil change in the middle without replacing the oil in the crankcase. The lack of combination of Goldberg and the instant case is that simple. No artisan having ordinary skill in that field of endeavor would be led to teach, suggest or be motivated to abort such an operation by committing such an error. Another simple analogy is the person who takes an automobile into the shop to have the winter tires removed and the summer tires replaced. The mechanic removes the winter tires and then puts the automobile on blocks, never replacing the summer tires. No skilled artisan would employ a method that aborts a tire change operation in the middle without substituting the summer timer for the winter ties. These simple situation's like the simple concept that no artisan would be led to abort dialysis without removing the dialysate from the peritoneum form the basis of the mutually exclusive nature of Goldberg and the supply chain container conversion of the instant case. The Goldberg reference and the instant case are not substitutable in this regard. Very simple, mutually exclusive and non-combinable and without the possibility of substitution. "Because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references, E*x parte Levengood, 28 USPQ2d 1300(Bd Pat. App. & Inter. 1993) See Also In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000)*(Court reversed obviousness rejection because there was no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention). *Al-Site Corp. v. VSI Ibt'l Inc. 174, F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).*

The detailed Office Action dated 03/28/07 has been carefully considered.

Distinguishing Technical Differences/Goldberg and the instant

Applicant applies the Graham factors in ascertaining the differences. Graham v. John Deere, 383 US, "The supreme Court reaffirmed and relied on the Graham three pronged test in its consideration and determination of obviousness in the fact situations presented in *Sakraida v. Ag Pro., 425 US, 273 189 USPQ 449, 426 US 955 (1976) and Andersons-Black Rock Inc. v. Pavement Salvage Co., 396 US 57, 163 USPQ 673 (1969).*

1) Goldberg reference Figure 1-4 are unrelated to container conversion egress. Figure 1-4 only deal with drainage and ingressing. Without container egressing in Figures 1-4 these figures cannot be combined with the container conversion of the instant case.

2)The suggested combination as defined by the Examiner would effectively abort the container ingressing parts of the Goldberg reference. The instant case required that a container that has egressed its fluids be converted in a clean(not biologically contaminated by a patient) and empty condition. Such container conversion of the instant case would abort all ingressing phases of the Goldberg reference, whether or not the application was for peritoneal dialysis or for irrigation/aspiration as defined for bladder irrigation.

3)The combination would not work because the fluid as egressed in the Goldberg reference is used as the fluent material vehicle to remove the dialysate or the irrigated material. No artisan would

conceive of removing a container before the aspiration is completed by the container ingressing fluent material vehicle. This condition prevents container conversion in the manner as revealed in the instant case.

4) To combine these two cases, and to convert the container as taught by the instant case, would mean that the dialysate would be left in the peritoneum without removal, If repeated, the combination would suffocate the patient by pressurizing the diaphragm, restricting the patients tidal volume leading the suffocation, cyanosis and even death by lack of oxygen. The Goldberg reference recites (Col 13-lines 33-35) "The 28 ports of this preferred embodiment will support a full week of peritoneal dialysis in which four batches of dialysate are introduced and drained daily. No one would introduce dialysate, disconnect the container by the supply chain container conversion in the manner defined by the instant case, and leave dialysate in the peritoneum never allowing it to function as the vehicle to remove body waste as required by peritoneal dialysis. The repeated combination would kill patients by suffocation.

5) None of the elements/limitations in Figure 5-13 are required to pour fluids from a container as would be carried out in the manner defined by the instant case for pouring as a part of supply chain container conversion of the instant case.

6) All of the ingressing elements/limitations disclosed in Goldberg (Figure 5-13) are not required to ingress fluent materials into the converted container of the instant case. The manifolds and all of its associated elements, connections etc.

7)Other dispositive questions that arise in an inquiry as to the un-combinability of the Goldberg reference and the instant case are.

a) Peritoneal dialysis requires an indwelling catheter-what if there is no indwelling catheter.
b)An indwelling catheter requires a surgical procedure for implantation-what if no procedure had been performed.
c)Explain how and why to provide dialysate to a patient who does not have renal failure.
d) Assuming arguendo, a patient has had an indwelling peritoneal catheter implanted, how would pouring fluids onto a patient result in getting such fluids into the peritoneum.
e)How would pouring fluids as contemplated by the instant case be considered closed, as required by Goldberg.
f)An indwelling catheter is implanted into one place and not moved. How would this accommodate the moving of an egressed converted container as carried out by the instant case during a supply chain container conversion using a container having the requisite clean and empty conditions.
g)How much dialysate continually introduced into the patient, if the container is converted as with the instant case, will it take for a patient to suffocate.
h)If the egressed container is converted by the instant case, how will the body contaminants get removed from the body. The dialysate is the fluid responsible as the vehicle for cleansing the peritoneal cavity in order to rid of its biologically produced body wastes.
I) Converting the container as required by the instant case would abort the dialysate ingressing steps of Goldberg. In other words the ingressing parts of Goldberg Claims1, 2, 3, 4, & 5 would be eliminated/aborted:

a)Combination aborts Goldberg dialysis-Claim 1(Col. 13, line 63 to Col. 4-line 6)-no ingressing.
b)Combination aborts Goldberg dialysis-Claim 3(Col. 14-lines 27-38)-no ingressing.
c)Combination aborts Goldberg dialysis-Claim 4(Col. 14-line 60 to Co. 15-line 8)-no ingressing.

d)Combination aborts Goldberg dialysis-Claim 5(Col. 16-line 7 to Co. 16-line 23)-no ingressing.

"Where the teachings of the prior art conflict, the Examiner must weigh the suggestive power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another." *In re Young, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991).* If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).* "The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose." "If the proposed modification or combination of the prior art would change the principle of operations of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Riatti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).*"The suggested combinations of references would require a substantial reconstruction and redesign of the elements shown in (the primary reference) as well as a change in the basic principle under which the primary reference is construction was designed to operate." "Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart, 531, F.2d 1048, 189 USPQ 143 (CCPA 1976).*

Harmful effects of the combination:
a) Overfilling peritoneum without container ingress leads to loss to tidal volume(diaphragm motion)
b) Overfilling peritoneum without container ingress leads to suffocation.
c) Overfilling peritoneum without container ingress leads to diaphragm loss of function.
d) Overfilling of peritoneum without container ingress leads to patient death.

No skilled artisan would consider such a combination:

Using the "same container" is moot in a 103 analysis when the dispositive question is what would have led a person having ordinary skill in the related art to do what the inventor has done.

The Examiners remarks are moot in view of following common knowledge and common sense in the field.

a)An indwelling catheter(catheter for egress such that the objective requiring an absolutely "closed" system is accomplished, versus the "Pouring operation" of the instant case.
b)The Goldberg problem is catheter born infection-from an indwelling catheter.
c)The Goldberg root cause is exposure to the atmosphere.
d)Atmospheric exposure led Goldberg to devise a completely closed system.
e)What would the combination be when a patient without renal failure is encountered.
f)What would the combination be when a patient without an indwelling catheter is encountered.
g)Even with an indwelling catheter it would be impossible to get fluid into the peritoneum by pouring.
h) What would be the success of getting fluid into the peritoneum where there are no connections as required by Goldberg(i.e. by pouring without physical connection means)
i)Pouring would expose the fluid to the atmosphere.
j)Pouring would certainly contaminate the fluids.
k)Pouring would effectively give the patient a bath, not succeed in dialysis.
l)Pouring would prevent fluid from getting into the abdomen.
m)Examiner has not explained how a pouring operation would protect fluids from the atmosphere.

n)Examiner has not explained how body wastes would be removed from the combination as suggested by the Examiner.
o)Examiner has not explained how violating a well established procedure in its middle(not removing dialysate) would lead a person of ordinary skill to combine these two references.
p) The Examiner has not explained how a full container might function to additionally ingress.
q)The Examiner has not explained, based on principles of sterility and contamination, how a biologically contaminated container would be suitable for container conversion when cleanliness is required.
r)The Examiner has not explained how the patient will get an infection absent an indwelling catheter(the basis for the Goldberg manifold and its related Claims 1-5.)
s) The Examiner has not explained the combination between an open pouring system having no physical egressing connecting components with a closed indwelling implant physically implanted and in contact with a patient body which provide the root cause-infection and atmospheric exposure.

These aforesaid reasons, inter alia, are just a few of the reasons why the Applicant of the instant case did not look to back to 1986, the date of the Goldberg patent issuance. Violating the dialysis/irrigation aspiration procedure by the container conversion of the instant case defines these two cases being non-relevant art. Goldberg is an irrelevant reference insofar as container converting differs.

"Where the teachings of the prior art conflict, the Examiner must weigh the suggestive power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another." *In re Young, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991).* If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).* "The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose." "If the proposed modification or combination of the prior art would change the principle of operations of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Riatti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).*"The suggested combinations of references would require a substantial reconstruction and redesign of the elements shown in (the primary reference) as well as a change in the basic principle under which the primary reference is construction was designed to operate." "Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart, 531, F.2d 1048, 189 USPQ 143 (CCPA 1976).*

Applicant believes the easiest method of making the distinguishing "Graham inquiry" legally based differences between the Goldberg reference and the instant case is to look carefully at the container egress and ingress teachings of the Goldberg reference to carefully examine what is revealed, and what is not revealed, in the Goldberg reference. A bona fide Graham inquiry may accurately be made on these egress/ingress facts in evidence as they are so disclosed by Goldberg. Applicant intends to show that this factual inquiry (Graham) will lead to a legal conclusion that the Goldberg reference and the instant case cannot be combined, in the view of an ordinarily skilled artisan. Furthermore, this legal inquiry will show on the factual technological merits that the Goldberg reference, and the instant case are mutually and exclusively un-combinable, to any legal standard and the any representation of the expected success of the combination would be grounded in impermissible hindsight reconstruction. Applicant maintains, as Applicant has maintained since the

Examiner's err in bringing Goldberg into this prosecution, that no legal prima facie case can be grounded in law basing a 103 rejection of the instant case in reliance on Goldberg.

"When the art in question is relatively simple, as is the case here the opportunity to judge by hindsight is particularly tempting." *McGinley v. Franklin Sports (2001) In re Ruiz, 357 F.3d at 1286. US v. Adams 383 US 39, 148 USPQ 1966 decided with Graham v. John Deere, supra, provided a further test for non-obviousness, i.e. an invention in non-obvious if the prior art "teaches away" or otherwise "deters investigation" in the invention".* We explained that conclusory statement such as those here provided do not fulfill the agency's obligation to explain all material facts relating to a motivation to combine." *In re Lee, 277 F.3d 1341, 1344.*

The Applicant would like to draw the Examiner's attention to Goldberg Col. 4-lines 55-65. This describes briefly Figures 1-4. Each of these figures reveals a drainage only device. This knowledge is probative to the lack of combination whereas drainage is commensurate with only container ingress. No container egress is involved with the Figures 1-4. When no egress is involved in Fig. 1-4 then no container conversion can be said to exist in these Figures 1-4. (Applicant hereinafter refers to Figures 1-4 individually and collectively as a group as "the container ingress Figures" (Col 4.-lines 55-65) of Goldberg)).

The Applicant would like to draw the Examiners attention to Goldberg Col. 4- line 66 to Col. 5 lines 1-25.

These Figures 5-13 reveals container egress, insofar as it relates to peritoneal dialysis and or bladder irrigation. (Applicant hereinafter refers to Figures 5-13 individually and collectively as "the container egress Figures" (Col. 4-line 66 to Col. 5-lines 1-25) of Goldberg.

Further to understand what elements/limitations are revealed in Goldberg for the purposes of Goldberg's "objective reach" and "means" for carrying out container egress and container ingress as taught by Goldberg, the Applicant lists for the Examiners convenience the elements and limitations by Figure number as is revealed by such container ingress (Fig. 5-13) as revealed in the Goldberg specification, and, for container lack of egress(drainage only) (Figures 1-4) and such container as defined in the Goldberg specification for container ingress as revealed by container egress Figures 5-13.

Further the Applicant will show the distinguishing supply chain legal differences with respect to Goldberg's third preferred embodiment (Col. 12-line 64 to Col 13-line35) upon which the Examiner relies using a broad conclusory statement that the "same container" is used for egress and ingress. The Applicant will show how, based on common sense principles of sterility, and the requisite supply chain container conversion requirements, why an artisan, having ordinary skill in the art would never inflict the harmful effects suggested by the Examiners combination of the Goldberg reference with the instant case.

Each of the key technological concepts of container egress and container ingress, have significant sterility supply chain implications, and, as known by skilled artisans as common knowledge, and common sense, said key technological concepts of container egress and container ingress further define boundaries of combinability. Applicant hopes to show the Examiner about the common sense/common knowledge sterility principles so the Examiner will consider such sterility principles in applying the Goldberg reference in a 103 rejection in this case. Skilled artisans apply principles of sterility in their endeavors to make inventions successful. Skilled artisans rely on principles of

sterility as a roadmap to devising successful improvements. Skilled artisans define device application based on their common sense/common knowledge of sterility principles so as to refrain from harming patients, and so the endeavors of such efforts are serviceable. The Examiner's remarks lack of these common sterility tenants, and lacks an application of these common knowledge/common sense sterility principles, and without such and understanding of these sterility principals the Examiner rejection lack such critical skill/knowledge base to determine "what would have led a person of ordinary skill in the art to do what the inventor has done" as in the instant case in order to properly determine a 103 rejection. Furthermore, without an understanding of these sterility principles, that Examiner is without the requisite legal/factual foundation to determine under Section 103, if there exists any teaching suggestion or motivation by Romano/the instant case looking back to Goldberg to do what Goldberg has done and vice versa. There is no correlation between these two cases. The undersigned did not incorporate Goldberg into the supplychain container conversion of the instant case.

Claim 1 as divided into container egress and container ingress.

-For container Egress-(Col 13-lines 53-62)-pouring would fail, but would contaminate/injure patients.

-For container Ingress – (Col 13-line 63 to Col 4-line 6) aborted by the combination.

Claim 2 is dependent from claim 1 and falls under the arguments made herein for clam 1 as it relates to distinguishing legal differences-aborted by the combination.

Claim 3 as divided into container egress and container ingress.

-For container Egress-(Col. 14-lines 10-26)-pouring would fail, but would contaminate injure patients.

-For containers ingress-(Col 14-lines 27-38)-aborted by the combination.

Claim 4 divided into container egress and container ingress.

-For container Egress (Col. 14-lines 39-59)-pouring would fail, but would contaminate/injure patients.

-For container Ingress (Col 14-line 60 to Col. 15-line8)aborted by the combination.

Claim 5 divided into container egress and container ingress.

-For container Egress (Col 15-line 9 to column 16-line 6)-pouring would fail, but would contaminate/injure patients.

-For container Ingress (Col 16-line 7 to column 16-line 23)-aborted by the combination.

By combining Goldberg and the instant case, the Examier has aborted/terminated the aforesaid "ingress" aspects of Goldberg Claims 1, 2, 3, 4, & 5. This is done in err.

In order for the Examiner to understand the distinguishing legal differences, it is important to connect the container egress/ingress elements/limitations of the Goldberg Figures found it the specifications as facts in proof, with the container egress/ingress elements/limitation of the Goldberg claims, and then ask the aforementioned fundamental questions about comparing the differences between the Goldberg reference and the instant case, in order to make the factual "Graham inquiries" as defined by law. This is the only way to arrive a proper "legal conclusion with respect to a 103 rejection as maintained by the Examiner.

The Examiner must keep in mind that the common principles of sterility are required in order to successfully convert a container(I.E. the container is clean and empty) in the manner revealed in the instant case.

NOTE: Goldberg Figures 1-4 are ***silent*** with respect to container egress.

The Goldberg container egress elements/limitations begin in Col. 8-line9. "Now turning to figure 5- These container egress elements/limitation include: irrigation manifold 130, (similar to manifold 10), output port 132, check valve 134, valve 136, input port 140, valve 150, snap on cap 160, anchor points 138, rack 180.

"Referring now to Fig. 6(Col 9-line 1) belt 210, strip of cloth 214, four fasteners 212, lightweight fabric vest 280, vest fasteners 282, belt(210) end sections 216/218, eight containers 220, conduits 230, valves 240, unfolded containers 220a, volumetric scale 222, support net 290, hooks 292, eight input ports 250.

""Turning now to Fig. 7-8." (Col. 10 line 10). Belt 210, belt end section 216/218, hook and loop fasteners 213, central volume 300, inlet ports 250 and each of conduits 230.

" Fig 7a" (Col. 10-line14) -belt 210, central volume 300, inlet port 250, and conduits 230.

"Fig 7b"(Col 10-line 19)-belt 210, end section 218, end sections 216/218.

"Fig 8." (Col 10-line 25). Belt 210, recess 310, belt catheter 320, opening 312, flange 322, **indwelling catheter 330.**

"Fig. 9" (Col. 10-line 47) belt 210, ports 250, container conduits 230, central volume 300, flange 252, belt 210, adjacent conduits 230, folded containers 220, neck region 224, associated valve 240, port valves 260, valves 240, snap-on cap 270, flexible strap 272.

Column 12-line 18-"One current regimen of peritoneal dialysis involves introducing and draining two liter batches of dialysate four times a day. The belt 210 shown in Fig. 6-9 is well suited for this regimen, in that it includes 16 ports 250 and 16 two liter containers 220. This belt 210 can be used for four complete days of dialysis before it will have to be replaced"

This means that 8 liters of dialysate is introduced daily, and that 24 liters of dialysate will be introduced into the peritoneum of a patient in a four day period.

"Figs. 10 & 11". (Col. 12 line 25.) "Figs. 10 & 11 represent a second preferred embodiment of the dialysis belt of this invention. This embodiment is similar to that of Figs. 6-9 in that it includes 16 valved inlet ports 250 and 16 valved containers 220. For these, like components of the two embodiments are provided with like reference numbers"

"As best shown in Fig 11" (Col 12 line 32) Belt 340, internal partitions 342 belt interior 340, two manifold/chambers 350/360, extended belt length 340, 16 inlet ports 250, 16 valved containers 220, valves 240, **indwelling catheter 330,** three way valve 370, **inner belt catheter 334, outer belt catheter 336.**

"A third Preferred embodiment of the dialysis belt of this invention is shown in Figures 12 & 13" (Col 12-line 64) belt 380, 28 valved input/output ports 250, arranged along the underside of belt 380, ports 250, valve 260, snap-on ca 270.

"The belt 380 is designed to utilize the dialysate container (not shown) as a drainage container." "As before, the belt 380 is originally a sealed sterile unit in which all 28 of the valves 260 are closed. After the belt catheter is coupled to the indwelling catheter (not **shown in this view), dialysate is** introduced into the belt from a dialysate container which is coupled to one of the input/output ports 250 under sterile conditions. As before, each port 250 is used only once, and each valve 260 is kept closed until after the dialysate container has been connected.

"In this case however the dialysate container is not removed from the port 250 after the dialysate has been drained into the peritoneal cavity. Instead, the dialysate container is left connected to the port 250 until it is time to drain the dialysate from the peritoneal cavity. Then without ever removing the dialysate container, the used dialysate is drained into the same container from which it came. After the used dialysate has been returned to its container the associated valve 260 is closed and only then is the filled dialysate container removed from the ort 250"

"This embodiment provides the important advantages of low bulk and low cost. In that containers need not be sealed to the belt 380 prior to use, more ports 250 can be easily placed around the belt 380. Various numbers of ports may be supplied depending on the application.

(Col 13-lines 33-35) "**The 28 ports of this third preferred embodiment will support a full week of peritoneal dialysis in which four batches of dialysate are introduced (*container egress*) and drained** (*container ingress*) **daily"**

The examiners combination not only aborts the ingress aspects to Goldberg Claims 1-5, the Examiner combination aborts all container ingressing elements/limitation recited in association with Figures 5-13(the ingressing figures) aspect of. This is further proof that the combination is impossible.

The Goldberg reference reveals in claim 1, Col 13 lines 52 to Col 14 lines7)
"1) A device for introducing dialysate into and draining dialysate from, the peritoneal cavity f a human subject, said device comprising;"

"a first manifold;"

"means for transporting dialysate out of the first manifold for introduction into a human peritoneal cavity;"
"means for introducing dialysate into the first manifold, said introducing means including a plurality of separately valved input ports;"

The Goldberg reference reveals no egressing function in Figure 1 and Figure 2. The apparatus of Figures 1 & 2 are disclosed for drainage only. (Col 5 line 29) No egress comparison can be made in that regard. A distinguishing difference with the instant case. The instant case reveals egressing by pouring. The instant case reveals a container conversion that involves both egress and ingress with respect to a single container, said single container being adapted to be in the requisite conditions, requisite conditions precedent for the container conversion of the instant case. Applicant recited these structural differences in

Figures 1 & 2 of the Goldberg apparatus reveals for drainage ingressing (only): manifold 10, input port 50, four output ports 30, containers 20, containers 20a, support net 90, hook 92, snap on cap 70, anchor points 74 and rack 76, Fig. 2-manifold 10, central cavity 100 valve 60 port 50, strap 70, etc.

Technological distinguishing difference between the instant case and Goldberg insofar as it relates to Figures 1 & 2.

1) None of said elements/limitations teach egressing.(delta principle)
2) None of said elements/limitations teach delivery of sterile liquids.(unsatisfactory for)
3) None of said elements/limitations teach pouring.(inoperable for)

Applicant contents that the Goldberg reference would not be used in its normal operation as it is defined herein.

These differences should be given patentable weight. The dispositive question however, and based on a 103 rejection, is: What would have led an artisan of ordinary skill to combine Goldberg with the instant case? The answer is nothing. The two cases are mutually exclusive and each one teaches away from the other. Goldberg does not contemplate a supply chain container conversion. The applicant did not travel back in time to 1986 to use the dialysis system of Goldberg to arrive at the manner in which the instant case supply chain converts containers. Applicant contends that there are no market forces that could suggest or infer implicitly that there is a teaching, suggestion or motivation of the Applicant to cast the mind back 20 plus years to arrive at the container conversion of the instant case.

Claim 1 of the Goldberg reference then goes on to reveal for ingressing:

"a second manifold isolated from fluid communication with the first manifold;"

"means for transporting dialysate from the peritoneal cavity into the second manifold"

"means for receiving dialysate from the second manifold, said receiving means including a plurality of containers individually coupled to the second manifold by means of separately valved conduits; and;

"said first and second manifolds being provided in a longitudinal divided, elongated, flexible tubular member that is sized to fit around the abdomen of a human subject".

"The closed system drainage device of this invention" Goldberg (Col 6, line 58). Pouring, as revealed in the instant case is an open operations, and occurs during an egressing step, not in a drainage step insofar as it relates to a container conversion innovation.

Figure 3 of the Goldberg reference reveals: (Col 7, line 12) "Turning now to Figure 3, the closed system drainage device of this invention"

Figure 3 reveals "a portable urinary drainage device which is generally similar to that of (Fig. 1-2" Col. 7 lines 12-16.)

Figure 3 of the Goldberg reference reveals, for the purposes of drainage only:

"a central manifold 10', valved input port 50', valved output port 30', collapsible container 20', urinary drainage catheter 62', the entire assembly including manifold 10', the containers 20', and the input port 50', is manufactured as a single sealed unit which is sterilized prior to use"

Figure 3 reveals nothing about egressing. Each of the said elements/limitations define only in the area of ingressing as it relates to urinary drainage. Nothing to compare. No possibility of container conversion in a system where drainage/ingressing is the only disclosure.

Figure 4 of the Goldberg reference reveals "Fig. 4 shows a schematic view of a closed system drainage device of this invention arranged to receive drainage material froma closed wound suction device". (Col 7, lines 41-44).

Figure 4 reveals, closed wound suction device 150, manifold 10", valved input port 50", containers 20", conduit 152 conduit 154. (Col 7, lines 40-50).

No relation exists in Figure 4 to a container conversion. Figure 4 teaches drainage without reference to converting a container.

Figure 12 of the Goldberg reference reveals:

"A third preferred embodiment of the dialysis belt of this invention is shown in Figs. 12 and 13." Col. 12 lines 64-65).

Figure 12 & 13 reveals, belt 380, 28 valved input/output ports 250 along the underside f belt 380, valve 260, cap 270.

As revealed in Col 13, lines 6-35; "The belt 380 is designed to utilize the dialysate container (not shown) as a drainage container. As before, the belt 380 is originally a sealed sterile unit in which all 28 of the valves 260 are closed. After the belt catheter is coupled to the indwelling catheter (not shown in this view), dialysate is introduced into the belt from a dialysate container which is coupled to one of the input/output ports 250 under sterile conditions. As before, each port 250 is used only once, and each valve 260 is kept closed until after the dialysate container has been connected.

"In this case, however, the dialysate container is not removed from the port 250 after the dialysate has been drained into the peritoneal cavity. Instead, the dialysate container is left connected to the port 250 until it is time to drain the dialysate from the peritoneal cavity. Then without ever removing the dialysate container, the used dialysate is drained into the same container from which it came. After the used dialysate has been returned to its container the associated valve 260 is closed and only then is the filled dialysate container removed from the port 250.

Column 13 lines 6-35 reveals the opposite of what would be a supply chain container conversion as would be carried out in the manner of the instant case. Leaving a container connected is the reverse of container conversion. The instant case would require moving said container in its clean and empty condition.

This embodiment is an excellent example for applicant to teach the sterility principles common knowledge and commons sense that guides safety and effectiveness of artisans work. The

container is left connected and the sterility of the system is maintained throughout the drainage process. This requirement of the Goldberg system prevents, without traverse, any skilled artisan from considering the drainage application of Goldberg (Figure 5-13 and the ingress portion of claims 1-5) as dirty as suggested by the Examiner on page 4 and 5 of said office action. The Examiner errs in reciting that the Goldberg drainage operation represents "container recycling (page 4-line 7 where the Examiner remarks about claims 7 & 8 of the instant case)(The examiner errs in reciting the Goldberg drainage/ingress operation converts from a clean supply side(20) to a waste receptacle (dirty side)-on page 5 lines1 & 2 of said office action. These comments are made without the common knowledge/commons sense of a skilled artisan having knowledge of the fundamental tenets of sterility principles. Therefore these remarks are made in error. Applicant contends the examiner has erred on page 5 of said office action remarking about clams 12-14 that the Goldberg reference will reduce the amount of containers. Compared to what? Applicant suggests that the Goldberg reference does no such container reduction. Such is impossible in a pre-planned procedure and that no container reduction is achieved by Goldberg. What Goldberg does achieve is to reduce the vast numbers of container introduced by Goldberg itself. This however has no supply chain impact whatsoever. Goldberg is just removing its own increased number of container, back down to the status quo number of container before the volume of container numbers were increased only as a result of the number of valves Goldberg attaches to the manifold.

This is proved by evidence from the Goldberg specification, in the Goldberg reference in column 13 lines 28-35 wherein the Goldberg specification recites. "**This embodiment provides the important advantages of low bulk and low cost"((***the only "lowering" is the lowering of the containers increased only by necessity of the Goldberg manifold/belt-nothing else-no supply chain impact whatsoever),no relation to favorably impact that of the peritoneal dialysis procedure itself))"***In that* ***that containers need not be sealed to the belt 380 prior to use,"*** *(the belt ports dictate the increase in container potential-not the dialysis procedure and not the supply chain)* **"more ports 250 can be easily placed around belt 380".***(the only reason is to provide more room for ports 250-no supply chain motive/objective-no reduction in containers(as suggested by the Examiner) as it may impact the supply chain in the manner of the instant case)(just reducing the multiples of containers introduced "only" by the necessity of Goldberg's closed system and the number of ports that may now be placed on the belt 380 as a result of not providing a multiplicity of container's (the Goldberg's increased number of belt container's this third preferred embodiment purports to reduce) pre-sealed to the manifold/belts)* **"Various numbers of ports may be supplied, depending on the application. The 28 ports of this preferred embodiment will support a full week of peritoneal dialysis in which four batches of dialysate are introduced and drained daily".**

"This embodiment provides the important advantages of low bulk and low cost. In that containers need not be sealed to the belt prior to use, more ports 250 can be easily placed around belt 380. Various numbers of ports may be supplied, depending on the application. The 28 ports of this third embodiment will support a full week of peritoneal dialysis in which four batches of dialysate are introduced and drained daily"

It is noted: On page 2 of said office action; "The drawings dated 08 December 2003 are acceptable for examination purposes only. Upon allowance, new formal drawings will be required.

Applicant will provide new formal drawings upon allowance.

It is noted: On page 2 of said office action; "This application currently names joint inventors..... applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider applicability of 35 USC 1-3c and potential 35 USC 102(e), (f(, or (g) prior art under 35 USC 103(a).

The subject matter of the instant case is commonly owned. This statement is a provisional statement whereas a statement cannot be made as any claims not actually allowed by the Examiner in the instant case.

It is noted: On page 2 of said office action; "Claims 5-14 and 19-24 are rejected under 35 USC 103(a) as being unpatentable over Goldberg. Regarding claims 5 & 6, Goldberg discloses a supply chain method.

Applicant contends the Goldberg reference discloses a procedure for carrying out dialysis. Such a procedure is not a supply chain method as is defined by the instant case. Applicant believes the supply chain method of the instant case is patentably distinct over the Goldberg dialysis procedure.

It is noted: On page 3 of said office action the Examiner recites elements a-g in error as if said elements a-g read on the elements of claims 5 and 6 of the instant case. The Examiner fails to include all limitations of claims 5 & 6 of the instant case, such as "cap" and Pouring". These limitations provide distinguishing recognition between a supply chain container conversion involving "pouring" containers, as found on drawing sheets 1-7, 10-14 and 16-19 of the instant case and the closed apparatus as found in the Goldberg reference.

Applicant contends that the instant case, and the Goldberg references, when combined discredit each other in multiple ways on the technical merits, and that the Goldberg reference and the instant case are not combinable under an obviousness 103 type of rejection for the following reasons:

It is noted: On page 3 of said office action; "It is noted that when the device is being used to output dialysate to a patient, line (320, 330) will at least be under a partial vacuum because the system is closed."

Applicant believes this Examiners comment leads toward distinguishing patentable differences between the instant case and the Goldberg reference. The instant case defines vacuum pressure differently than that the Examiner references. Page 8 lines 11-16 of the instant case recites "Difficulties exists with the use of the certain pour bottles when integrated in a high negative pressure vacuum collection system. Difficulties also exist with the use of intravenous solution containers when integrated in a high negative vacuum system as commonly used in suction/vacuum collection of surgical waste materials. Negative vacuum draw pressure, at times up to -1 atmospheric pressure is common for drawing surgical waste materials from a surgical site into collection receptacles" Applicant contends that it would be impossible to operate a vacuum collection systems as defined by the Examiner (in Goldberg) as "CLOSED". The Goldberg reference is positively recited as closed. (see the following numbered references recited below representing quotes in evidence-the Goldberg reference showing this evidentiary statement)(#1, #11, #12, #14, #15, #16, #17, #18, #20, #22, #23, #24, #26, #37-(the instant case is not a close system-Goldberg distinguishes from the instant open system "column 2 line 14 "not true closed systems"), #45, #46, #49, #62, #67,#68 #79, #81, #87, #88, #89, #90, #91, #92, #94, #95, #96, #108, #127, #135, .The foregoing 34 evidentiary representations found in the Goldberg reference

patentably distinguish from the instant case on the technical merits. No one looking to establish an open system would ever look to an absolutely closed system. No prima facie case can form a 103 rejection by the combination of the Goldberg reference and the instant case. The instant case is open for pouring during egress and also open during waste ingress. This is technologically and scientifically correct because the up to -1 atmosphere of forces provided by a vacuum, displaces air/atmosphere displacement which must move into and thorough the instant system. The instant case defines an open inlet in a suction as an open draw path to accommodate said vacuum and said force movement. See drawing sheets 14, 15, 17 and 19 of the instant case.(wand # 19 of each sheet and the arrows defining the movement of vacuum forces, air, waste material flow/draw towards the neck of a container.) Applicant does not understand the Examiners remarks "'will at least be under a partial vacuum because the system is closed". The Goldberg system is indeed closed for both egress and ingress(the foregoing #'s). The instant case is indeed open for both egress and ingress. A patentably distinguishing difference. Applicant also contends a patentably distinguishing technical difference between "sealed" and "closed" of the Goldberg reference whereas the entire Goldberg system is closed, sealed off to the atmosphere, whereas the instant case seals a path that draws the atmosphere into the converted container of the instant case with enough force to ingress waste material. This fact is enough itself to defeat Goldberg on a 103 rejection. They are discrediting technological differences.

Applicant contends that the Examiner errs in defining 320, 330, as a vacuum draw path. Applicant contends that the forgoing facts overcome by the preponderance of the evidence any 103 rejection based on two technologically uncombinable references as the Goldberg reference and the instant case. Applicant is at a loss as to why someone would be led to make the combination.

It is noted: On page 4 of said office action; "Regarding claims 7 & 8, Goldberg teaches that the containers are integrated into a waste collection system (fig. 4 & 12) and that the sterile fluid containers are recycled as waste containers (col. 3, line 51-col. 4 line 53; Col. 12, line 64-col 13 line 27.

Applicant disagrees with the Examiners remark that Goldberg's containers are integrated into a waste collection system. (See remarks above) The Goldberg reference teaches a dialysis procedure. The Goldberg system is not a waste collection system and does not collect waste in the manner as the instant case includes a supply chain container conversion that functions in a separate vacuum system for collection of waste material. These are two technologically separate systems on the merits. A system that incorporates/operates a "closed only sterile procedure" cannot be recited as also a waste collection system as defined by the Examiner. The Goldberg heart is defined by maintenance of "closed conditions" from egress to ingress and maintenance of the sterility of both is at the heart of the Goldberg apparatus objective and design. Goldberg reveals the maintenance of sterility and closed conditions as the hallmark of its objective reach.

The Applicant invokes technologically sound merits based on skilled artisan's knowledge and common sense, as a skilled artisan to point out further uncombinability of the instant case and the Goldberg reference based on the following.

The combination of the Goldberg reference and the supply chain container conversion of the instant case would inflict great harm, and possible death to a health care patient, not to mention both case being defeated each at their objective heart.

Each of the following technological facts prevents the combination of the Goldberg reference with the instant case. The Examiners reciting that the Goldberg reference uses the same container for collection of used dialysate also does not consider the following incompatibility, and it does not consider the harmful effects of the supply chain conversion as it would be applied to Goldberg, in order to achieve the container conversion of the instant case.

The following is recited with an expectation of success, or expectation serviceability, which in each example, fails on both. Such a failure would suggest a lack of teach, suggestion or motivation.

It is noted: On page 5 of the office action; "Regarding claims 9-11, Goldberg teaches that the sterile fluid container (clean side of a supply) (20) is converted to a waist(waste) receptacle (dirty disposal side) in a disposal chain.

The Examiner errs technologically in that there does not exist a dirty disposal side during ingress of dialysate whereas this portion of the Goldberg reference is considered part of the "sterile procedure" with no possibility to convert the Goldberg container to dirty. (See remarks above)This is common knowledge and common sense to an artisan who is familiar with sterile procedures. No skilled artisan would characterize any portion of the Goldberg sterile procedure "as dirty"..it is not, it is considered sterile (clean) until the procedure is completed(after full ingress of used dialysate).

Threaded container is not the turning point in a 103 rejection. Other common knowledge, common sense factors known by skilled artisans would prevent leading such skilled artisans to combine the Goldberg reference with the instant case. Skill in such areas as sterile technique, sterile procedure, surgical procedure(in so far as it is required to implant a dialysis catheter) leads skilled artisans to avoid certain activities which would, if performed, intentionally infect a patient, induce cyanosis in a patient, asphyxiate a patient, suffocation of the patient by impingement of diaphragm motion leading to seriously impede lung capacity(tidal volume) or cause unintended patient death by loading the peritoneum with dialysate such that the diaphragm cannot move. This skill (knowledge base) of a skilled artisan, and how such common knowledge would prevent combination as suggested by the Examiner, will become more technologically apparent on the merits involving such skill, by the following explanations of why no one of ordinary skill would be led to combine these references as suggested by the Examiner. Combining these references as a whole would have harmful effects, and prevent the successful operation of both the Goldberg reference and the instant case. The following facts will prove that these references are mutually exclusive, and not combinable, and that no artisan having the ordinary skill necessary to achieve serviceable results in these mutually exclusive arts would be led to combine Goldberg with the instant case.

Using the "same container" is moot in view of the following common knowledge.

1)Indwelling catheter(catheter for egress such that the objective requiring absolute "closed" is accomplished. Vs. pouring-no combination.

2) Goldberg problem is catheter born infection-no combination.
-root cause exposure to the atmosphere.
-atmospheric exposure led Goldberg to a completely closed system.

3)Patient without renal failure –defines no combination.
4)Patient without a indwelling catheter(the egress closed requirement)-no combination.
5)Even with catheter-how to get fluids in by pouring-impossible-no combination.
6)Pouring would contaminate-no combination.
7)Pouring would prevent fluid from going in-no combination.
8) How pouring would protect the fluid from atmospheric exposure contamination-no combination.
9)Termination(aborting dialysis) by conversion of the container of the instant case.
-proper conditions of a container conversion of the instant case-no combination.
-empty.
-clean
-improper conditions of a Goldberg container conversion-no combination.
-full
-biologically contaminated

10) Killing a patient by continued combination-no combination.
-look at tidal volume.
-find where is says four batches a day.
11) converting the container of the instant case, on top of killing the patient-no combination.
-how will the used dialysate be collected.
-what are the ill effects of not removing the dialysate
-a weeks worth of dialysate would stall out the diaphragm.

12) How will the patient get an infection by the instant case if there is no indwelling catheter?

13) contact infection vs. air born infection-no combination.

14)Why an implant catheter system would combine with a system not requiring an implant-no combination.

15)Open with no physical contact vs. closed with indwelling implant physical contact-no combination.

16) Further-provider take the Hippocratic oath-do no harm-no combination.

17) 103 made without the common knowledge of a skilled artisan or sterility principles.

18) Supply chain container conversion occurs after egress and before ingress essentially aborting the Goldberg procedureno-combination.
-dialysis device would not be used in the instant manner in its normal operation.
-not suitable for its intended purpose.
-changing the principle of operation.
-unsatisfactory for its intended purpose.

19) Mutually exclusive teaching away from each other-no combination.
-No teaching suggestion or motivation
-The instant case would not be led by Goldberg because of the opposing principles as stated herein.

Goldberg facts teaching manifold system closed bonding/sealing

#1--Column 3 lines 21-32. One of the principle advantages of this improved drainage device and method is that each of the multiple containers can be filled and removed from the manifold **without ever opening the device to atmosphere during use**. When drainage begins, the entire device complete with a number of containers already attached to the manifold is a **sealed sterile unit.** ***Containers are sequentially filled*** and removed but the removal of individual containers is performed **only after the respective valve has been closed and the container isolated.**

#2--Column 3 line 44-49. Furthermore, each of the individual containers can be made of a ***collapsible material which can be folded into compact*** volume for storage before use. In this way a compact drainage device can be made which is readily stored and transported before use and is relatively low in bulk during use.

#3--Column 3 line 67-Column 4 line 1. Preferably, each container is provided with a ***dry sterile catheter*** and each capped input port is also ***dry and sterile***.

#4--Column 5 lines 31-46. this drainage manifold 10, is generally tubular in structure which is provided with a valved input port 50 and four valved output ports 30. The ***collapsible thin wall*** container 20 is ***sealed to each of the output ports 30***. In Figure 1, three of these containers 20 are shown ***collapsed and folded*** for storage into ***small packets*** and one of the containers 20a is shown unfolded ready to receive fluid from the manifold 10. Preferably, each container if formed of a flexible plastic material such a vinyl polyethylene or some other suitable material. The support net 90 is provided which can be positioned around an unfolded container 20a, by means of a hook 92 from manifold 10. The net 90 serves to support a major part of the weight of fluid contained in container 20a thereby permitting the use of *thin low bulk materials for the container 20.*

#5--Column 5 line 65-Column 6 line 2. Each of the valved output ports 30 includes a valve 40 which ***operates to selectively seal the port 30***. Each ***valve 40 includes a flange 32 sealed to the manifold 10***. Each output port 30 extends into the interior of the manifold 10. Each container 20 includes a narrow ***neck region 24 which is sealed to one of the input ports 30.***

#6--Column 6 lines 3-23. Then ***manifold*** is preferably formed from an ***extruded tube*** of vinyl of some other suitable plastic. Standard push pull valves such as valve model 320TE manufactured by Hawlkey of Paramus NJ are used to ***reliably seal the associated input port 50*** and output port 30 against contamination leakage and infection. The entire device, including the manifold 10, the foldable containers 20, and the input port 50 **forms a single sealed unit which is assembled under standard clean room conditions and then sterilized for use.** *Standard adhesive or heat sealing techniques* can be used to *bond* the manifold 10 the containers 20, and the ports 30,50 together to form a **sealed leak proof unit.** Whatever sealing technique is used, however should provide **reliable leak proof seals which form impermeable barriers to contamination and infection.**

#7--Column 6 lines 27-28. **As mentioned, the device is originally sterilized** with input port 50 closed and capped.

#8--Column 6 lines 33-36. An alternative embodiments, the drainage catheter can be sealed to the input port 50 during the manufacturing process and the entire assembly including the catheter can be sterilized as a unit.

#9--Column 7 lines 16-23. As before, the central manifold 10 is provided with a valved input port ***50' and four output ports 30' each of which is connected to a collapsible container 20'***. The input port 50' is adapted to connection with a urinary drainage catheter 62' **and the entire assembly, including the manifold 10', the container 20', and the input port 50' is manufactured as a single sealed unit which is sterilized prior to use.**

#10--Column 7 lines 44-47. Once again, the drainage device includes a manifold 10", a valve input port 50", and several containers 20" ***connected*** to the manifold 10" by valved output ports 30".

#11--Column 7 lines 51-59. The suction device 150 can be a conventional ***closed*** wound suction device and is operated in a conventional manner except that the suction device 150 is periodically ***emptied*** through the manifold 10' into one of the attached containers 20' ***without ever opening*** **either the suction device 150 of the manifold 10' to the atmosphere. As before the closed system drainage device operates to reduce contamination and results in retrograde infection of the patient.**

#12--Column 8 lines 24-29. This irrigation manifold is manufactured under standard clean room conditions. The output port 132 is then closed by means of valve 136 and capped. Each of the input port 140 is capped and closed by means of the associated valve 150 and then the *entire sealed manifold assembly is sterilized*.

#13--Column 9 lines 42-65. A set of eight containers 220 is mounted on each side of the bottom portion of belt 210 by means of conduit 230 equipped with valve 240. These containers are preferably ***thin plastic bags*** formed of vinyl or polyethylene, for example, which can be compact and ***folded*** as shown in Figure 6 prior to use. **Each bag is sealed to the lower end of the associated valve 240 which is in turn sealed to the conduit 230 extending from the belt 210. Adhesives or heat sealing techniques may be used to secure the containers 220, valves 240, conduits 230, the belt 210 to form a single sealed leak proof unit which provides an impermeable barrier to contamination and infection**. Each of the containers 220 is ***originally folded*** into and small packet adjacent the associated valve 240. The use of these container will be explained below. Here it is enough to know that each container can be ***unfolded*** to its full size as shown by the unfolded container 220a.

#14--Column 10 lines 4-9. A set of eight input ports 250 is mounted on each side of the top of the belt 210. Each port 250 is a tubular structure which is provided with a valve 250 and a snap on cap 270. **Once again the port 250, valves 260, and belt 210 are bonded together to form a single sealed unit which forms an impermeable barrier to infection.**

#15--Column 10 lines 19-24. Figure 7b shows a cross section of the belt 210 and the flattened section 218. In this region the tubular belt 210 has been flattened and the two opposed sides of the belt have been **sealed** together to **prevent leakage** from or contamination of the belt 210 near the end section 216, 218.

#16--Column 10 lines 29-34. The belt catheter 320 passes through an opening 312 in the belt 210 and is bonded to the belt 210 vial a flange 322. Once again, it is important that *leak proof seal* be formed to prevent contamination or infection and heat sealing or adhesive *bonding techniques* may be used.

#17--Column 10 lines 47-66. Figure 9 shows a cross sectional view of the belt 210 showing the internal arrangement of port 250 and the container conduits 230. Each conduit 230 penetrates and is in fluid communication with the central volume 300. It is provided with an external flange 232 which is ***sealed*** against the outside of the belt 210. In order to increase the packaging density adjacent conduits 230 are staggered by about 20 degrees. This permits the ***folded containers*** 20 to overlap as best seen in Figure 6. **Each container 220 defines a narrow neck region 224, which is *sealed* to the lower portion of the associated valve 240. Each of the valves 240 is an *on-off valve which completely seals off* the interior of the belt 210 from infection when the valve 240 is closed.** In the presently preferred embodiment, low bulk, push pull valves are used in which the valve is used to open and pushed to close. Such valves are readily available in standard components valve model 320TE manufactured by Hawlkey-Roberts of Paramus NJ. is one example of such a valve.

#18--Column 11 lines 7-18. The belt 210 should be *assembled in a clean room* and then sterilized prior to use. Utilizing *standard manufacturing practices* for medical devices as outlined by the Food and Drug Administration. It should be understood that when belt 210 containers 220, and port 250 are assembled all valves 240, 260 are closed and the belt catheter 320 is *sealed prior to sterilization*. In this way the belt is delivered as a *single sterile unit ready for use*. In use, belt 210 acts as a manifold though which dialysate can be introduced into and removed from the peritoneal cavity with reduced incidence of infection.

#19--Column 11 lines 25-29. First a container dialysate (not shown) is coupled via a tube to one of the valves 260. **The valve 260 will be *dry and sterile* for it has been capped since its initial sterilization.**

#20--Column 11 line 66-Column 12 line 9. When proper precautions are taken to assure that each dialysate container is sterile, this use of each input port is only believed to reduce the incidence of infection. **Furthermore since all drainage containers 220 are sealed in place from the beginning, dialysis drainage is accomplished *without ever opening* the belt 210 to atmosphere. In this way , infection associated with drainage is reduced.** The belt 210 has been designed to minimize infection of the subject from dialysis contamination either when introduce into the subject or when drained.

#21--Column 12 lines 14-18. ***Only after*** each of the port can container has been used will the belt be replaced with a **new belt complete with a new set of sterile ports and folded containers.**

Goldberg facts teaching maintenance of a closed manifold system in use

#22--Abstract lines 2-4. The fluid receiving manifolds include a plurality of separately valved containers **sealed** to the manifold.

#23--Abstract lines 4-7. Each container is **filled in series** via the manifold and associated **valve is closed *before* the container is removed** from the manifold for disposal.

#24--abstract lines 7-8. Thus a **closed drainage system** is provided.

#25--Abstract line 10. Preferably **each port is used only once**.

#26--Abstract line 11-12. In each case the **port is kept closed *until*** it is coupled to a source of fluid and it **is re-closed *before*** the source of fluid is disconnected from the port.

#27--Abstract line 14. In this **contamination is further reduced**.

#28--Column 1 lines 14-15. The present invention is directed to improved devices and methods for **reducing infection**.

#29--Column 1 line 25-27. In these and other similar situations the **continued sterility of all associated devices used for.**

#30--Column 1 line 31-33. It is well recognized that conventional drainage devices are a prime source of infection of catheterized patients.

#31--Column 1 lines 37-38. and infection then ascends in a retrograde manner.

#32--Column 1 line 40. Such retrograde infection.

#34--Column 1 line 60-64. Retrograde infection in drainage devices is in many cases attributable to the fact that conventional drainage devices **are open systems** which are repeatedly open to atmosphere and therefore subject to contamination during use.

#35--Column 2 lines 1-5. After the evacuator becomes filled, it is emptied for re-use by removing the cap and expelling the collected fluid in the outlet. During this operation the anterior of the evacuator is exposed to the atmosphere and contamination of the evacuator may result.

#36--Column 2 line 10. This valve operates to close the outlet at all times.

#37--Column 2 line 14. But they are **not true closed systems** because the evacuators are periodically opened for purging it is still possible for them to be contaminated as a source of infection.

#38--Column 2 line 19. For **reducing the incidence of retrograde** infection due to contamination of drainage devices.

#39--Column 2 line 23. A second source of patient infection is contamination of devices for introducing fluid into the body.

#40--Column 2 line 33. In this approach the indwelling catheter is connected to and then disconnected from a number of container in **sequence**. The same connection point of the containers is **repeatedly brought into contact** with the dialysate and then exposed to the atmosphere.

#41--Column 2 line 38 & 40. This **repeated wetting** and exposure to atmosphere is believed to contribute to the contamination of the catheter and associated infection.

#42--Column 2 line 42. May become infected as they are connected to and disconnected from a number of containers of irrigation fluid in succession.

#43--Column 2 line 44. Thus a second important object of the present invention is to provide improved devices and methods for introducing fluid into human and animal subjects with reduced possibility of contamination thereby **improving sterility and reducing infection**.

#44--Column 2 line 53. which are **less susceptible to contamination** infection than devices and methods of the prior art.

#45--Column 2 line 56. According to a first feature of this invention, a **completely closed drainage** device is provided which the interior of the device need ***never be opened to the atmosphere*** during use.

#46--Column 3 line 1. and individual conduits are provided with valves which can be positioned to ***close off*** **the conduits therefore** ***isolating*** **the associated containers** from the manifold. Each of the conduits are ***severable at a point between the associated valve and the container.***

#47--Column 3 line 11. The associated valve is then **closed in order to isolate** this fluid filled container from the manifold.

#48--Column 3 line 14. The fluid filled container is then removed.

#49--Column 3 line 17-20. The separate container are then **sequentially filled** and then removed until either all the containers are filled or drainage from the subject is discontinued.
#50--Column 3 line 24. **Without ever opening the device to atmosphere during use.**

#51--Column 3 line 27-30. Containers are ***sequentially*** **filled and removed** but the removal of the individual containers is ***only*** performed ***only after*** **the respective valve has been closed** and the container isolated.

#52--Column 3 line 30-31. Preferably **each valve is capped and further sealed** from the environment.

#53--Column 3 line 35. Since the drained body fluid is **removed in a series** of containers.

#54--Column 3 line 44. Furthermore each of the individual containers can be made of ***collapsible*** **material which can be** ***folded*****.**

#55--Column 3 line 55. According the a second feature of this invention, an improved device for introducing fluid into the human body.

#56--Column 3 line 60-64. Each port is provided with a separate valve by means by which the **port may be isolated** form the manifold. Each port is preferably provided with a cap for **sealing the port** when not in use.

#57--Column 3 line 67-column 4 line 1. Preferably each container is provided with a **dry sterile** catheter and **each capped input port is dry and sterile.**

#58--Column 4 line 3-5. After the catheter is connected, the associated **valve is opened and fluid is allowed** to flow from the container into the body.

#59--Column 4 line 7. **When the container is emptied a second container is then connected** to the manifold via a second port.

#60--Column 4 line 8. In each case the associated port **valve is only opened after the container** has been connected to the port **and the valve is closed before** the container is removed. Preferably **each port is only used once**.

#61--Column 4 line 14. **by *never* using a port twice.**

#62--Column 4 line 27-31. the dialysis manifold is coupled to the peritoneal cavity of the subject and a **separate containers** are used as previously described to remove dialysis from the manifold ***without ever opening it to the atmosphere*.**

#63--Column 4 line 36. In this embodiment of the invention, containers of dialysate are **sequentially coupled** to different ports as before **each port is used only once to reduce infection.**

#64--Column 4 line 42. Instead the **container is left connected to the port** and the dialysate is then drained from the peritoneal cavity to the same container from which it came.

#65--Column 4 line 45. It is ***only then* that the container is removed** from the port.

#66--Column 4 line 46. This embodiment provides the important advantage that the total drainage capacity of the manifold is **no longer limited by the number of containers that can conventionally be stores** adjacent the manifold.

#67--Column 4 line 64. Figure 4 is a schematic view of a **drainage manifold coupled to a closed wound suction device.**

#68--Column 5 line 3-5. preferred embodiments of both the **closed drainage feature** and the multiple input port feature of the present invention.

#69--Column 5 line 33-34. A ***collapsible* thin walled** container 20 is sealed to each of the output ports.

#70--Column 5 line 36. **are shown collapsed and folded**.

#71--Column 5 line 42. can be positioned around an **unfolded container 20a.**

#72--Column 5 line 58. both ends of the manifold 10 are **sealed**.

#73--Column 5 line 59. Input port 50 includes a valve 60 which operates to ***selectively* seal the port** 50.

#74--Column 5 line 65. Each of the valved output ports 30 includes a valve 40 which **operates to *selectively* seal the port** 30.

#75--Column 6 line 1-2. Each container 20 includes a narrow neck region 24, which is **sealed to** one of the input ports 30.

#76--Column 6 line 8. **Reliably sealed,** the associated ports 50.

#77--Column 6 line 9. The entire device including the manifold 10, the foldable containers 20, and the input port 50 forms a *single sealed unit which is assembled* in a standard clean room conditions and the sterilized prior to use.

#78--Column 6 line 15. Whatever *sealing* technique is used, however, should provide *reliable, leak proof seals which from impermeable barriers* to contamination and infection.

#79--Column 6 line 20. Which is *closed and capped during manufacturing* process to ensure the continued sterility of the device.

#80--Column 6 line 23. In use the drainage device of Figures 1 & 2 functions as a **closed system** which receives fluid drained from the body.

#81--Column 6 line 26. **Without ever opening the drainage device.**

#82--Column 6 line 27. As mentioned, **the device is originally sterilized** with the **input port 50 closed and capped**.

#83--Column 6 line 33. In alternative embodiments, drainage catheter can be *sealed* to the input port 50 *during manufacturing, process entire assembly* the including the catheter can be sterilized as a unit.

#84--Column 6 line 37. **After** the input port 50 has been mated.

#85--Column 6 line 44. The associated valve 40 is **closed.**

#86--Column 6 line 49. Each of the containers 30 is preferably **filled in sequence so that no more than one container is receiving drained fluid at any given time.**

#87--Column 6 line 51. In each case the associated **valve 40 is closed** before the container is ***severed* thus the manifold is *never* opened to atmosphere** or contamination ***after*** it has been connected to the source of body fluid.

#88--Column 6 line 55. Large quantities of fluid can be drained over an extended period of time **without ever opening the system to atmosphere.**

#89--Column 6 line 58. The **closed system drainage device** of this invention.

#90--Column 7 line 5. Thus, this embodiment provides a **simple closed system drainage** device.

#91--Column 7 line 9. It is preferable to **use a closed system drainage device**.

#92--Column 7 line 12. Now turning to Figure 3 the **closed system drainage** device is well suited for use with ambulatory patients.

#93--Column 7 line 16. As before a central manifold 10' is provided with a valved input ort 50' and four valved output ports 30' each of which is connected to a **collapsible** container 20'.

#94--Column 7 line 41. Figure 4 shows a schematic view of a **closed system drainage** device of this invention ***arranged*** to receive drainage material from a **closed wound suction device.**

#95--Column 7 line 51. The suction device 150 can be conventional **closed wound suction device** and it is operated in the conventional manner except suction device 150 is **periodically emptied** through the manifold 10" into one of the attached containers 20" ***without ever*** **opening either the suction device *or* the manifold 10" to atmosphere**. As before the **closed system** drainage device ***operates to reduce*** contamination and resulting retrograde infection to the patient.

#96--Column 7 line 60. It should be apparent from the foregoing discussion that the **closed system drainage device** of this invention can be used either **with or without suction** devices in either fixed installation or portable embodiments.

#97--Column 8 line 3. In general these **devices include multiple separately valved input ports** each of which is preferably **used only once**. These ***devices and methods*** are well suited for **bladder irrigation, wound irrigation and other situations where sterile fluids are introduced to the** body.

#98--Column 8 line 14. This output port 132 is provided with a check valve 134 oriented to prevent fluid from entering the manifold 130 via the output port 132, and the **valve 136 which operates to selectively close the output port 132.**

#99--Column 8 line 26. The output port is then closed by means of the valve 136 and capped, each of the input ports 140 is capped and closed by means of the associated valve 150, and the *entire sealed manifold assembly is sterilized*.

#100--Column 8 line 31-39. In use the output port 132 is coupled to an irrigation catheter such as a bladder irrigation catheter, for example. As before, the catheter can be made an integral part of the output port 132 or the port 132 can be mated with a suitable catheter either before or after the catheter has been inserted into body. A container of irrigation solution **is then connected** to one of the input ports 140 and the associated **valve 150 is opened to *allow*** the solution to pass into the **manifold** 130 and out the output port into the body.

#101--Column 8 line 41. When a second container of nutrient is needed the valve 150 on the **input port 140 connected to the first container is closed** and the first container is removed.

#102--Column 8 line 44. Then the second container is coupled to a **fresh input port 140** that has not been previously used and the process is repeated. **Each input port is preferably used *only once*** to reduce the incidence of infection.

#103--Column 8 line 51. The multiple input port feature of the invention is not restricted to use in irrigation. It can be used in many situations where fluid from multiple sources must be introduced into the body **under sterile conditions**.

#104--Column 8 line 57. In each application the size of the manifold and the size and the number of input and output port should be chosen to fit the intended use.

#105--Column line 63. In this embodiment the output port is nothing more than the junction between the manifold and the catheter and the output port valve can be eliminated. This alternative embodiment is well suited for both collecting samples of a body fluid as well as introducing fluid into the body.

#106--Column 9 line 1. Referring now to Figure 6, both the multiple valved container feature of the invention and the multiple valved input port feature of the invention can be used together in a **manifold for peritoneal dialysis**.

#107--Column 9 lines 6-41. Includes features of the **garment** aspects of the belt.

#108--Column 9 line 47. Each **bag is *sealed*** to the lower end of the associated valve 250 which is in turn ***sealed*** **to a conduit 230** extending from the belt 210.

#109--Column 9 line 52. To form a *single sealed leak proof unit* which provides an impermeable barrier to contamination and infection.

#110--Column 9 line 57. Here it is enough to note that each container can be **unfolded to its full** size which is shown by the unfolded container 220a.

#111--Column 10 line 8. Once again the ports 250, valves 260 and belt 210 are *bonded* together to form a *single sealed unit* which forms an impermeable barrier to infection.

#112-Column 10 line 23. **have been *sealed*** **together to prevent** leakage from or contamination of belt 210 via the end sections 216,281.

#113--Column 10 line 31. Once again it is important that a ***leak proof seal*** be formed to prevent contamination or infection, and ***heat sealing*** or ***adhesive bonding techniques*** may be used.

#114--Column 10 line 52. **Sealed** against the outside.

#115--Column 10 line 54. Permits the **folded containers** 220 to overlap.

#116--Column 10 line 55. **Each container 220 defines a narrow neck region** 224 which is **sealed** to the lower portion of the associated valve. 240.

#117--Column 10 line 58. Each of the valves 240 is an on off valve which ***completely seals*** **off the** interior of the belt 210 from infection **when the valve 240 is *closed*.**

#118--Column 10 line 68-column 11 line 3. Each of the ports 250 also is in fluid communication with the central volume 300 and is **sealed to the exterior of the belt** 210 by a flange 252 on the port 250. The port valves 260 are preferably push pull valves, similar to the container valves 240.

#119--Column 11 line 7. The belt 210 should be assembled in a clean room and then sterilized prior to utilizing standard manufacturing practices for medical devices as outlined by the Food and Drug Administration.

#120--Column 11 line 14. I this way the belt is **delivered as a *single sterile unit*** ready for use.

#121--Column 11 line 16. In use the belt 210 acts as a manifold though which dialysate can be introduced and removed from the peritoneal cavity **with reduced incidence of infection.**

#122--Column 11 line 27. The valve 260 will be dry and sterile, or has been capped since its initial sterilization.

#123--Column 11 line 36. After the dialysate container has been emptied, the associated **valve 260 is closed** and the container is removed and the cap 270 is replaced. In this way the port 250 is **closed by the valve 260 before it is exposed to the atmosphere** therefore reducing contamination and infection.

#124--Column 1 line 42. The dialysate is allowed to remain in the peritoneal **cavity for a period of time** and is **then** drained from the peritoneal cavity via the belt 210 into one of containers 220. Prior to this, a selected container is unfolded and is placed within the support net 290. The associated **valve 240 is *then opened*** and dialysate flows from the central volume 300, via the conduit 230 and the valve 240 into the container 220. After the container is filled, the **associated valve 240 is *then closed*** and the filled container 220 is removed from the belt 210 by ***severing*** the neck of the bag below the valve 240. The ***severed*** **container** 220 and its contents are then discarded.

#125--Column 11 line 55. Because the container 220 is *not removed until after* the associated valve 240 has been *closed*, belt 210 is never open to atmosphere during drainage. Instead the central volume remains closed and uncontaminated.

#126--Column 11 line 60. The next batch of dialysate to be used is then connected to a second inlet **port valve 260 one which has not previously been used and the entire procedure is repeated.** In each case a **fresh input port 250 and a fresh container 220 are used**. Because no input port **250 is used twice, it is *always* a dry sterile input port valve 260 which is mated with the dialysate container.**

#127--Column 12 line 1. Furthermore, since all the drainage containers 220 are *sealed in place from the beginning*, dialysate drainage is accomplished ***without ever opening*** **the belt to atmosphere**. In this way infection associated with drainage is reduced.

#128--Column 12 line 7. The belt 210 has been designed to minimize infection of the subject from dialysate contamination either when introduced into the subject or drained.

#129--Column 12 line 14. Only after each of the ports of the containers has been used will the belt be replaced with a new belt complete **with a new set of sterile ports and folded containers.**

#130--Column 12 line 29. Like components of the two embodiments are provided with like reference numbers. "This comment refers to Figures 6-11."

#131--Column 12 line 32. As best shown in Figure 11, the belt 340 is divided by an internal partition 342 which divides the interior of the belt into two manifolds.

#132--Column 12 line 50. ***The embodiment of Figures 10 & 11 is used in much the same manner as that of Figures 6-9,*** except that for introducing dialysate into the peritoneal cavity the

three way valve 370 is set n the first position which couples the inner belt catheter 334 and the indwelling catheter 330; for draining dialysate valve 370 is set in the second position, which couples the outer belt catheter 336 to the indwelling catheter 330.

#133--Column 12 line 58. A principle advantage of this embodiment is that fresh ***dialysate is not mixed*** with previously drained dialysate in the belt 340.

#134--Column 12 line 64. A third preferred embodiment of this invention is shown in Figures 12 & 13. In this embodiment belt 380 defines only a single internal volume. The belt is provided with 28 valved input output port 250 arranged along the underside.

#135--Column 13 line 7. As before, the belt 380 is ***originally a sealed sterile unit*** in which all 28 of the valves 20 are ***closed***. After the belt catheter is coupled to the indwelling catheter, dialysate is introduced into the belt from a dialysate container which is coupled to one of the input/output ports 250 under sterile conditions. **As before each port 250 *is used only once* and each valve 260 is *kept closed until after* the dialysate container has been connected.**

#136--Column 13 line 17. In this case however, the dialysate container is not removed from the port 250. After the dialysate has been drained into the peritoneal cavity. Instead the dialysate container is **left connected to the port 250 until it is time to** drain the dialysate from the peritoneal cavity. The ***without ever removing*** the dialysate container, the used dialysate is drained ***from the same container from which it came***. After the used dialysate has been returned t its container, **the associated valve 260 is closed** and ***only then is the filled dialysate container removed from the port 250***.

#137--Column 13 line 28. This embodiment provides the important advantage of low bulk and low cost. In that container need not be sealed to the belt 380 prior to use. ***More ports 250 can be easily placed around the belt 380***. Various numbers of ports may be supplied, depending on the application. The 28 ports of this third preferred embodiment will support a full week of peritoneal dialysis in which four batches of dialysate is introduced and drained daily.

#138--Column 14 line 47. Such changes and modifications can be made ***without departing*** from the spirit and scope of the present invention ***without diminishing its attendant advantages***. It is therefore intended that such changes and modification be covered by the following claims.

The Examiner has rejected the instant case, several times now based on one small jist, or thrust written in the Goldberg reference, without taking the reference as a whole. When taking Goldberg as a whole, Applicant holds Goldberg as non-analogous art. The Examiner compares a well established procedure, that when combined with the instant supply chian method, would abort said dialysis procedure, leaving said Goldberg procedure incomplete. No skilled artisan would be led to provide any device with the objective of leaving dialysate in the body, when the objective is to remove said dialysate, the dialysate being the vehicle to remove and rinse waste from the body under a condition of renal compromise. No skilled artisan would be led to provide any irrigation/aspiration device with the objective of aborting to the extent of omitting the aspiration. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention" *W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).*

Applicant amends these claims for personal and business reasons, and not because the Examiner has established a prima facie 103 subject matter legal basis for rejection of the claims.

Applicant submits amended claims 4-30 for the record in a condition for which the Applicant believes are allowable, and/or are in a better condition for appeal. Applicant believes independent claims 4, 5 & 7 are in a condition for allowance, and therefore the remaining claims depending from them are also in a condition for allowance. In an independent claim is non-obvious under 35 USC 103, then any claim depending therefrom is non-obvious. *In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).*

Applicant believes evidence has shown that there is no reasonable expectation of success by the combination suggested by the Examiner *(In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).*

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)* "All words in a claim must be considered in judging the patentability of that claim against the prior art" *In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)*

Should the Examiner consider necessary or desirable any formal changes anywhere I the specification, claims and/or drawings, then it is respectfully asked that such changes be made by Examiners amendment, if the Examiner feels this would facilitate passage of the instant case to issuance. Alternatively should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

Respectfully Submitted for the record,

MedIndica-Pak, Inc./Applicant

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06/22/2007

Dated

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